

## REMARKS

Upon entry of the present amendment, claims 32 and 93-96 are pending. The amendment to claim 32 and the addition of new claims 93-96 finds support *inter alia* at pages 4-7 of the specification and in Examples 1 and 2.

### **THE 35 U.S.C. §103(A) REJECTIONS**

The Examiner maintained the rejection of claims 32, 33 and 62-63 under 35 U.S.C. §103(a) as being unpatentable over Scott *et al.* ("Scott") in view of US Patent No. 5,618,913 ("Brange"), alleging that Scott teaches the use of a 24- hour infusion of saline (control) or a glucose potassium insulin infusion (16 U of human soluble insulin, 20 mmole of KCL in 500 ml 10% dextrose) at 100 ml/h, while Brange is cited as disclosing rapid-acting human insulin analogs such as Asp<sup>B28</sup> human insulin. Thus, the Examiner has alleged that the combined references result in the claimed invention, and as such, the claimed invention was *prima facie* obvious.

In reply, Applicants submit that this rejection is rendered moot by the amendment to claim 32 and the addition of claims 93-96 as Scott, alone or in combination with Brange does not teach or suggest treatment of a critically ill patient or a CIPNP patient with insulin, an insulin analogue or an insulin derivative in an amount effective to reduce the incidence of mortality (claim 32), CIPNP (claim 93), sepsis (claim 94), renal failure (claim 95) or multiple organ failure (claim 96) in said patient. Indeed, Scott report that there was no difference in the clinical outcomes measured (including mortality) by Scott between the treated and control groups (see Table 3 of Scott).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

The Examiner has also rejected claims 32, 34 and 62-63 under 35 U.S.C. §103(a) as being unpatentable over Scott *et al.* ("Scott") in view of US Patent No. 5,547,929 ("Anderson"), alleging that Scott teaches the use of a 24- hour infusion of saline (control) or a glucose potassium insulin infusion (16 U of human soluble insulin, 20 mmole of KCL in 500 ml 10% dextrose) at 100 ml/h, while Anderson is cited as disclosing monomeric insulin analogs such as Lys<sup>B28</sup>, Pro<sup>B29</sup> human insulin having a property of ultra rapid time action profile as compared to insulin. Thus, the Examiner has alleged that the combined references result in the claimed invention, and as such, the claimed invention was *prima facie* obvious.

---

For the reasons stated above, Applicants assert that neither **Scott** alone, nor in combination with **Anderson**, teaches or suggests the presently claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

The Examiner has also rejected claims 35, 36 and 64-65 under 35 U.S.C. §103(a) as being unpatentable over Scott *et al.* ("Scott") in view of US Patent No. 5,750,497 ("Havelund"), alleging that **Scott** teaches the use of a 24- hour infusion of saline (control) or a glucose potassium insulin infusion (16 U of human soluble insulin, 20 mmole of KCL in 500 ml 10% dextrose) at 100 ml/h, while **Havelund** is cited as disclosing some active derivatives of insulin analogs, such as des-Thr<sup>B30</sup> human insulin γ Lys<sup>B29</sup> tetradecanoyl having an improved property such as protracted profile of action and solubility at physiological pH as compared to insulin. Thus, the Examiner has alleged that the combined references result in the claimed invention, and as such, the claimed invention was *prima facie* obvious.

For the reasons stated above, Applicants assert that neither **Scott** alone, nor in combination with **Havelund**, teaches or suggests the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

In light of the present amendment and the arguments above, Applicants believe that the present rejections under 35 U.S.C. §103(a) are now moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejections.

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested.

The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: October 31, 2007

/Richard W. Bork, Reg. No. 36,459/

Richard W. Bork, Reg. No. 36,459

Novo Nordisk Inc.

Customer Number 23650

(609) 987-5800

Use the following customer number for all correspondence regarding this application

**23650**

PATENT TRADEMARK OFFICE